

Appl. No. 10/783,648
Amtd. Dated January 2, 2009
Reply to Office Action of July 1, 2008

REMARKS/ARGUMENTS

Claims 1-16 were pending in this application.

Claims 1-2, 4-12 and 14-16 were rejected under 35 USC 103(a) as being unpatentable over Eggers et al. US20060106649. Claims 3 and 13 were rejected under 35 USC 103(a) as being unpatentable over Eggers et al. in view of the Examiner's Official Notice that it is well known in the art to provide power on sleep and power off modes in networked medical devices. These rejections are respectfully traversed for the reasons that follow.

Eggers et al. disclose a patient care device having multiple configuration databases stored in its memory. Each configuration database includes protocols, operating limits, rule sets or features that collectively define an operating environment or "personality" of the device. Selection of the specific configuration database for use is based at least in part upon patient-specific information, such as patient age, size, medical characteristics, or patient or device location, which can be obtained from any location in a distributed hospital network. [Abstract] Paragraph [0033] states that the allowable configuration databases are preferably stored in the (primary) memory 56 of the interface unit 14, although it is contemplated that one or more of the configuration databases might be stored within modules 16, 18, 20, 22. The memory 56 could be an internal hard disk, a removable storage media including a flash drive, or that a portion could even be stored in RAM.

Paragraph [0034], which was cited by the Examiner, merely discloses that the memory of the patient care device can contain different configuration databases that can be selected for different locations or patient care areas within a hospital. FIG. 3 and paragraph [0036] cited by the Examiner disclose the typical structure of the configuration databases and discuss that the databases may include links to other databases.

Paragraph [0051] merely describes a multi-step infusion protocol that allows various rates/volumes during a protocol. Paragraph [0055] discloses that the configuration databases of the patient care devices can be selected on the device or periodically downloaded from a server on the unit. Paragraph [0057] discloses that information can be transferred within the hospital network to cause the patient care device to alter its personality or select a configuration database based upon such information or a particular treatment location.

Paragraph [0063] merely discloses that a hospital committee agrees upon, defines or establishes the configuration databases and enters them through a drug library editor.

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Paragraph [0064] discloses that the pumps are then updated by transferring configuration databases into some or all of the devices. Transfer typically occurs over a network transmission channel 34. Alternatively, removable media, PCs, PDAs or any other appropriate means can be used for transferring the information into the patient care devices 12.

Paragraphs [0066] and [0070] disclose that selection or modification of the specific active configuration database can be done manually by the caregiver at the device after it has first been powered up according to FIG. 7, by scanning information on a patient wristband or machine readable label on a medication container, or automatically by the system based on the operative connection of the device to a particular department's local area network within the hospital network or information from lab results or monitoring functional units connected to the device. Eggers et al. disclose that a new or modified configuration database can be transmitted to the primary memory of patient care device.

However, as the Examiner admits, there is no suggestion that an existing configuration database is left in the primary memory of the medical device while a new configuration database is transmitted to a cache memory within the device and held in waiting in the cache memory of the medical device until a trigger event occurs. There is nothing to suggest that the replacing of the existing drug library in primary memory of the medical device with the new drug library does not happen immediately when the new drug library is selected or transmitted to the medical device. In other words, at best Eggers et al. disclose transmitting a new drug library to the patient care device or selecting a subset of an existing drug library resident in the primary memory of the device. With the structure and method disclosed by Eggers et al. there is absolutely no need to cache a new drug library because there are already a plurality of active configuration databases stored within the primary memory of the medical device. All one needs to do is identify or choose a particular configuration database to use or transmit a new one. Thus, although cache structures may be known in the general computer art, one skilled in the art of electronic medical devices would be disinclined to modify Eggers et al. to use a cache memory to store a new drug library or the extra steps of caching the new drug library and waiting for a triggering event before replacing the current active drug library with the new drug library, absent the impermissible use of hindsight in view of the present application. Such a modification of Eggers et al. would also be detrimental to its primary advantages. The present invention recognizes the challenges of modern medical practice and that there are times when the medical device

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should not accept new drug library, but hold it in waiting for a specific triggering event. One such situation is when the medical device is performing an infusion or other therapy with the existing drug library and needs to complete the therapy. The present invention avoids the need to pause or stop the current infusion or move the device as taught by Eggers et al. See dependent claims 9, 10, 15 and 16.

For the above reasons it is believed that independent claims 1 and 11 are patentable over the prior art. Claims 2-10 depend from claim 1 and at least derive their patentability therefrom. Claims 12-16 depend from claim 11 and at least derive their patentability therefrom.

Furthermore, claims 3 and 13 are believed to be patentable in their own right because Eggers et al also fail to disclose that a power-on sleep mode or a power-off mode is used as a triggering event to replace the drug library in the primary memory of the medical device with the new drug library stored in the cache memory of the medical device. The Examiner's use of Official Notice regarding medical devices having various modes is both unpersuasive and irrelevant unless it can be shown that the specific modes recited are used to trigger a movement of a drug library from the cache memory to the primary memory of a medical device after the new drug library has been transmitted to the medical device. The mere fact that such modes might exist on a medical device does not make a *prima facie* case of obviousness. The only relevant teaching from Eggers et al. is that a selection of a drug library or configuration database might be made at startup (FIG. 7 and [0066]-[0067]). Startup is a fully ready for operation mode that is clearly different from a power-on but sleeping mode or a power-off mode. Thus, claims 3 and 13 are patentable over the prior art.

New claims 17-20 are submitted for consideration. New claims 17-20 are supported by FIG. 19 and paragraphs [0099]-[0105] of the original specification as published. Further support is found in FIGS. 4A, 6, 15, 15A, 16, 21, and 26 and page 2, lines 9-13; page 6, lines 11-15; and page 17, lines 7-25 of co-pending and commonly owned published application WO2005050526 whose US counterpart was incorporated by reference in its entirety in paragraph [0105] of the present application.

A Petition for Extension of Time by three (3) months from October 1, 2008 to January 2, 2009 is submitted herewith along with the authorization for payment of the appropriate fees. No further extensions or fees are believed to be due in connection with this paper. However, the Commissioner is authorized to consider this a request for any necessary extension and charge our Deposit Account, 50-3118 for any additional fees (or credit any

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over payments) in association with this communication. A timely and favorable response on the merits of the claims is respectfully requested.

Respectfully submitted,
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